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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,691	02/09/2001	Oliver Danne	81640	7836

7590 12/02/2003

KREIGSMAN & KREIGSMAN
665 FRANKLIN STREET
FRAMINGHAM, MA 01702

EXAMINER

COLE, MONIQUE T

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 12/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

cb/p

Office Action Summary	Applicati n No.	Applicant(s)	
	09/762,691	DANNE ET AL.	
	Examiner	Art Unit	
	Monique T. Cole	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the corresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>9</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Examiner Suggestions

The Examiner recommends that the following changes be made to the claims to place the application in better condition for allowance: in claim 1, all instances of "and/or minor ischemic myocardial damage namely" be replaced with "involving" & all instances of "and ischemic membrane destruction" be deleted. Claims 3, 4, 5 & 7 should be amended similarly as claim 1.

Claim 9 & 12 should be cancelled (see discussion of claim 9 below) and claims 13 & 14 should be rewritten in independent form.

Specification

The attempt to incorporate subject matter into this application by reference to prior publications mentioned in the specification is improper because these references should be submitted in a proper Information Disclosure Statement in order to be fully considered. Proper correction is required.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for recognizing and diagnosing acute myocardial infarction, does not reasonably provide enablement for all acute coronary syndromes. The specification does not

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enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

3. Upon inspection of the instant specification, it appears that all correlations are directed towards CCTD and myocardial infarction. While Applicant does point out that levels of CCTD below the limit may be indicative of other coronary troubles, such a correlation does not appear to be absolute, as is the case with myocardial infarctions. In fact, it appears that more of a correlation is made between such coronary troubles as angina pectoris and troponin levels. At best, on page 22, the specification does seem to support instable angina pectoris along with myocardial infarction which may be diagnosed based on choline measurements. The instant claims, however, are directed to CCTD measurement and content and do not consider troponin levels. Thus, the instant claims do not seem to be commensurate in scope with instant disclosure. Further clarification and/or correction is required.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: there are no steps presented in the claim to allow one to practice the means for use in the diagnosis of coronary syndromes. What process must one of

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ordinary skill go through in order to accomplish this claim's goal? Further clarification is required.

Response to Arguments

6. Applicant's arguments filed 11/17 have been fully considered but they are not persuasive. Applicant has argued that the specification is enabled. However much of the specification is speculative as to the relationship between CCTD and various forms of angina. There are some instances where in some forms of angina there is no CCTD elevation. Further clarification is required.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monique T. Cole whose telephone number is 703-305-0447. The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 703-308-4037. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0661.



Monique T. Cole
Examiner
Art Unit 1743

MC